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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,777	03/24/2004	Lennart Mucke	UCAL-280	8698

24353 7590 05/03/2006

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EXAMINER	
MONTANARI, DAVID A	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,777	MUCKE ET AL.	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, and 16-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants arguments and amendments filed 2/9/2006 have been entered.

2. Claims 4-7, and 11-12 are amended.

3. Claims 16-28 are newly added.

4. The rejection of claims 1, 3-8, and 10-14 under 35 USC 102(b) is withdrawn.

5. The rejection of claims 2 and 9 under 35 USC 103(a) is withdrawn.

6. Claims 1-14 and 16-28 are examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-6, 14, 20, and 25 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants have stated in amendment that support for the amended claims can be found in paragraphs 0019, 0033, 0037, 0038, 0045, 0047, and 0052 of the instant specification. However, support for the specific amendments, Arc mRNA, and ERK mRNA cannot be found in the instant specification. An examination of said paragraphs, further does not support the claimed

amendments. Applicants is invited to cite page and line number to identify the specific support for the claimed amendments.

Claims 1-14 and 16-28 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting an amyloid peptide-related impairment of spatial learning comprising detecting a level of a calbindin mRNA or polypeptide, a neruopeptide Y mRNA or polypeptide, or an α-actinin II mRNA or polypeptide in the hippocampus of a transgenic mouse whose genome comprises a transgene encoding a mutant amyloid precursor protein (APP) wherein detection of said mRNA or polypeptides in said transgenic mouse differs from the levels of said mRNA or polypeptides in the hippocampus of a normal control mouse and a method for identifying a candidate agent for treating an amyloid peptide-related impairment of spatial learning comprising administering a test agent to a transgenic mouse whose genome comprises a transgene encoding a mutant APP and detecting a level of a calbindin mRNA or polypeptide, a neruopeptide Y mRNA or polypeptide, or an α-actinin II mRNA or polypeptide *in vitro* in hippocampal tissue of said mouse and comparing said mRNA or polypeptide levels in hippocampal tissue to said transgenic mouse not administered said test agent, does not reasonably provide enablement for a method of detecting an amyloid peptide-related neurological disorder comprising detecting a level of any calcium-responsive gene product in the brain of any non-human animal model wherein detection of a level of any calcium-responsive gene product differs from the levels of any calcium-responsive gene product of a normal control mouse and for a method of identifying a candidate agent for treating an amyloid peptide-related neurological disorder comprising administering a test agent to any non-

human animal model of an amyloid peptide-related neurological disorder and detecting the level of any calcium-responsive gene product in vitro in the brain tissue of said non-human animal and comparing the levels of said gene products to said non-human animal not administered said test agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record in the office action mailed 8/10/2005.

Response to Arguments

Applicants argue in amendment filed 2/9/2006 that the specification provides for four calcium-responsive gene products whose levels are altered in an animal model of an amyloid peptide-related neurological disorder. Applicants continue to argue how the courts clearly explain the level of undue experimentation and burden of further research in relation to the requirements of 35 USC 112 first paragraph with regard to enablement. Applicants continue that the specification provides for other animal models for amyloid peptide-related neurological disorders in paragraph 0069 in the specification. These arguments are not persuasive. At issue is the non-human animal model of an amyloid peptide-related neurological disorder. Yes there are other non-human animal models of an amyloid peptide-related neurological disorder, but they are all mouse models of an amyloid peptide-related neurological disorder. As discussed in the previous office action, the claims are drawn to a "model" non-human animal of a disorder. That the non-human animal is a model means that predictably said animal will have an amyloid peptide-related neurological phenotype. The question is, can any non-human animal be a model

of an amyloid peptide-related neurological disorder? As discussed in the previous office action, the answer is no. Not any non-human animal can be a model of an amyloid-peptide related neurological disorder, however, mice as discussed in the scope of enablement are an exemplary model for said disorder. Applicants argue that the specification has provided four working examples of calcium responsive gene products. However the claims dare drawn to any calcium-responsive gene product, of which this genus would be huge. The claims are not solely drawn to those four calcium responsive genes given the claims current breadth. Applicants argue that one of skill in the art would find it reasonable to expect that other calcium responsive gene products would respond the similarly to the four describe calcium genes. However, as discussed below, applicants have only argued and the specification only teaches the function of the four genes and have not discussed nor taught, what is the common structure that would lead to an expectation by the skilled artisan that all other genes in the genus would behave as the four calcium genes taught by the instant specification. Thus for reasons of record in the office action mailed 8/10/2005 and above the rejection is maintained.

Claims 1-14 and 16-28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in the office action mailed 8/10/2005.

Response to Arguments

Applicants argue in amendment filed 2/9/2006 that is incorrect in stating that the instant application only teaches four genes that affected in level in response to expression of amyloid peptide. Applicants continue to argue that description of the four species discussed in the working examples is sufficient to satisfy the written description requirement, and that applicants have provided a description of the genus in paragraph 0021 of the specification. This is not persuasive. The specification does not teach what is the common relationship among calcium-responsive gene products that would lead to a change in their level due to an amyloid peptide-related neurological disorder. Specifically the instant specification teaches only how the four genes are related by function, but what is the core structure? Related function alone, does not indicate that applicant was in possession of all calcium responsive gene products. Absent from the instant specification is the teaching that, besides function, what is the common relationship among calcium responsive gene products that makes them responsive to an amyloid peptide-related neurological disorder. Applicants have discussed that intracellular calcium ion concentration will vary the protein and/or mRNA levels of calcium gene products, however what is the common identifying characteristics that would teach the skilled artisan that applicant was in possession at the time of filing of all calcium-responsive gene products that would change in level due to an amyloid peptide-related neurological disorder? Applicants have taught five calcium-responsive gene that are known to change in level due to an amyloid peptide-related neurological disorder, however applicants have not taught what is the common identifying characteristic among these five that would further describe that other calcium-responsive gene

products would change in level due to an amyloid peptide-related neurological disorder. Thus for reasons of record in the office action mailed 8/10/2005 and above the rejection is maintained.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Montanari, Ph.D.

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER